

practice regulations set forth in this part and, if any studies are currently being conducted, that the quality and integrity of such studies have not been seriously compromised. A disqualified testing facility that wishes to be so reinstated shall present in writing to the Commissioner reasons why it believes it should be reinstated and a detailed description of the corrective actions it has taken or intends to take to assure that the acts or omissions which led to its disqualification will not recur. The Commissioner may condition reinstatement upon the testing facility being found in compliance with the good laboratory practice regulations upon an inspection. If a testing facility is reinstated, the Commissioner shall so notify the testing facility and all organizations and persons who were notified, under §58.213 of the disqualification of the testing facility. A determination that a testing facility has been reinstated is disclosable to the public under part 20 of this chapter.

PART 60—PATENT TERM RESTORATION

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SOURCE: 53 FR 7305, Mar. 7, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 60.1 Scope.

(a) This part sets forth procedures and requirements for the Food and Drug Administration's review of applications for the extension of the term of certain patents under 35 U.S.C. 156. Patent term restoration is available for certain patents related to drug products (as defined in 35 U.S.C. 156(f)(2)), and to medical devices, food additives, or color additives subject to regulation under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act. Food and Drug Administration actions in this area include:

- (1) Assisting the United States Patent and Trademark Office in determining eligibility for patent term restoration;
- (2) Determining the length of a product's regulatory review period;
- (3) If petitioned, reviewing and ruling on due diligence challenges to the Food and Drug Administration's regulatory review period determinations; and
- (4) Conducting hearings to review initial Food and Drug Administration findings on due diligence challenges.

(b) References in this part to the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[53 FR 7305, Mar. 7, 1988, as amended at 57 FR 56261, Nov. 27, 1992]

§ 60.2 Purpose.

(a) The purpose of this part is to establish a thorough yet efficient process for the Food and Drug Administration review of patent term restoration applications. To achieve this purpose, the regulations are intended to:

- (1) Facilitate determinations of patent term restoration eligibility and regulatory review period length, and